Message

From: Kleinstreuer, Nicole (NIH/NIEHS) [E] [nicole.kleinstreuer@nih.gov]

Sent: 5/17/2021 9:13:32 PM

To: Amber Daniel [adaniel@ils-inc.com]; John Gordon, PhD [jgordon@cpsc.gov]; Suzanne Fitzpatrick

[Suzanne.Fitzpatrick@fda.hhs.gov]; Elijah Petersen, PhD [elijah.petersen@nist.gov]; warren.casey@nih.gov; Perron,

Monique [Perron.Monique@epa.gov]; david allen [dallen@ils-inc.com]; Agnes Karmaus [akarmaus@ils-inc.com]

Subject: Re: VWG Sub-group Discussion

Attachments: ICCVAM - Validation and Regulatory Acceptance of Toxicological Test Methods - frame work ejp nck.docx

Hi all,

Please see attached for an updated version with Section 4 expanded out substantially into subsections. I've also added another section at the end on facilitating acceptance/application. If you could take a look and provide your comments on this it would be great.

Thanks Nicole

PS – Elijah, the subsections you added to Section 8 did not populate in the table of contents, maybe bc it wasn't done using the same formatting? But they are there at the bottom.

From: "Kleinstreuer, Nicole (NIH/NIEHS) [E]" < nicole.kleinstreuer@nih.gov>

Date: Monday, May 17, 2021 at 1:55 PM

To: Amber Daniel <adaniel@ils-inc.com>, "John Gordon, PhD" <jgordon@cpsc.gov>, "Fitzpatrick, Suzanne (FDA/CFSAN)" <Suzanne.Fitzpatrick@fda.hhs.gov>, "Elijah Petersen, PhD" <elijah.petersen@nist.gov>, "Kleinstreuer, Nicole (NIH/NIEHS) [E]" <nicole.kleinstreuer@nih.gov>, "Casey, Warren (NIH/NIEHS) [E]" <warren.casey@nih.gov>, "Monique Perron, PhD" <Perron.Monique@epa.gov>, Dave Allen <dallen@ils-inc.com>, Agnes Karmaus <akarmaus@ils-inc.com>

Subject: Re: VWG Sub-group Discussion

Here are 4 papers I mentioned that are relevant to the international harmonization section. Will send updated outline shortly.

Thanks

N

From: adaniel@ils-inc.com

When: 1:00 PM - 2:00 PM May 17, 2021 Subject: VWG Sub-group Discussion

Location: online, via Webex

Please hold this time on your calendars in case a meeting of the VWG sub-group is needed to discuss the draft outline for the guidance document.

VWG Sub-group: Outline Discussion

Monday, May 17, 2021

1:00 PM | (UTC-04:00) Eastern Time (US & Canada) | 1 hr

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